the market formulated out of approximate 600 basic drugs.

(b) WHO's essential drug list of 1985 gives about 350 drugs in different therapeutic heads and when these drugs would be formulated by large number of manufacturers in the country under different dosage forms such as tablets, capsules, injections, ointments, oral liquids, the number of formulations moving in the market would appear many. However, the list of drugs used for Primary Health Centre and sub-centres together is very restrictive and the number does not exceed 58 drugs.

(c) Drugs reported to be withdrawn in some countries and continue to be marketed in other countries do not figure in the WHO list.

(d) and (e) Out of 37 drugs, reported to be withdrawn in some countries, 19 drugs were never approved to be marketed in India, 11 drugs have been withdrawn from the market and remaining 7 drugs namely, (1) Enteroquinol, (ii) Phenformin, (iii) Hydroxyquinoline derivatives, (iv) Phenylbutazone / Oxyphenbutazone (v) High dose Lynestrenol products, (vi) Piperazine and (vii) Analgin have been allowed for continued marketing in consultation with experts as the experts felt that there were no adequate reasoning for withdrawal of these drugs and these drugs are considered useful by medical practitioners.

Drugs technical advisory board on the Analgin and its combination

487 SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to Unstarred Question 2961 given in the Rajya Sabha on the 3rd December, 1986 and state:

(a) whether ban of marketing of Analgin has been considered by Drugs Technical Advisory Board;

(b) if so, what is the decision arrived at by the Committee;

(c) whether Analgin alone and in combination with other drugs have been found dangerous and fatal in number of countries in different regions, what are the reasons for considering it to be safe in India;

(d) what are the specific areas where the situation of India differ from other countries, where this drug has been banned;

(e) whether adverse reports have been published throughout the world; what are the reasons to allow this dangerous drug for human consumption in India;

(f) whether it is a fact that number of substitute drugs are available in the country without any adverse report; and

(g) if so, what are the names of those drugs?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) The Drugs Technical Advisory Board while examining the justification for continued marketing of Analgin had advised to wait for the results of the Drug Surveillance Study of Analgin conducted under the supervision of a collaborative group at Boston in the United States. While the Boston study have not pin pointed a greater absolute risk of Analgin when compared with other pain killers in terms of its alleged adverse reaction of lowering a particular type of white blood cells, the Drugs Technical Advisory Board is yet to meet and review the Boston study report for giving its considered opinion on the subject.

(c) to (e) The occurrence of agranulocytosis as an adverse reaction to Analgin was known right from the time the drug was introduced in the market and what has been found in later years is to compile its incidence in a limited geographical population in some countries having facilities to do so. It is not that the drug was found to be specially dangerous in some countries While some countries have withdrawn Analgin, the drug continues to be marketed in many countries. The experts consulted in India after the completion of the Boston study had considered that Analgin is a potent pain killer

and when used discriminately it benefit outweighs the possible risks. However, Government, with the help of an expert committee is investigating the rationality for continued marketing of combinations of Analgin with other drugs.

(f) It is not true that other pain killers moving in the market are totally free from side effects and every drug has its characteristic side effects.

(g) Does not arise.

Marketing clearance for new drugs, drug combinations and vaccines

488 SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that both clearance for marketing of new drugs, combination drugs and vaccines as well as manufacturing permissions are granted by State drug Authorities;

(b) if so, whether it is a fact that State drugs authorities are neither having qualified nor experienced officers to take a decision about the rationality or irrationality of drugs;

(c) what is the direction of the Government in regard to clearance of new drugs, combination of drugs and vaccines in the country;

(d) whether Government have proposed certain guideline in this regard; and

(e) if so, what are the details of the same?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) As per the "Guidelines on Introduction of New Drugs" combination of known drugs and vaccines would fall under the definition of "new drugs" and as such permission to market and manufacture new drugs is required to be granted by the Drugs Controller (India). However, the guidelines are not yet statutory and some States have cleared certain combinations of drugs and vaccines for marketing in consultation with their experts.

State Drug Control Authorities in consultation with experts generally license formulations.

(c) to (e) The "Guidelines on Introduction of New Drugs" gives a clear-cut definition as to what constitutes a new drug, defines the various phases of clinical trials, safety data and other pre-clinical data that are required to be submitted for examination before clinical trials permission could be granted to an applicant. Both pre-clinical and clinical data that are required to be submitted for a new drug for consideration of its marketing are also given in the guidelines. It also gives the types of data that are required for consideration of marketing permission of various possible types of combinations.

Linking of Sector-37, NOIDA with Kendriya Terminal by D.T.C.

489. SHRI M. KADHARSHA: Will the Minister of SURFACE TRANSPORT be pleased to state:

(a) whether representations have been received by D.T.C. authorities recently regarding linking of Sector-37, NOIDA with Kendriya Terminal, if so, the action taken by Government on each of such demand;

(b) whether Government propose to start some bus routes from that area for Kendriya Terminal in the near future; if so, by when; and

(c) if not, the reasons therefor?

THE MINISTER OF STATE OF THE MINISTRY OF SURFACE TRANSPORT (SHRI RAJESH PILOT): (a) to (c) Yes Sir. A trip at 0640 hrs. on Route No. 346 has been provided from Sector-37 NOIDA for Kendriya Terminal and vice-versa at 1315 hrs. There is no proposal for further augmentation as the existing service is considered adequate.